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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,071	09/19/2006	Hidetoshi Ito	3712174.00608	3798

29175 7590 10/18/2010

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EXAMINER	
LACLAIR, DARCY D	

ART UNIT	PAPER NUMBER
1763	

NOTIFICATION DATE	DELIVERY MODE
10/18/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/599,071	ITO ET AL.	
	Examiner	Art Unit	
	Darcy D. LaClair	1763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8 and 10-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8 and 10-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. All outstanding rejections, except for those maintained below are withdrawn in light of the amendment filed on **8/3/2010**.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The new grounds of rejection set forth below are necessitated by applicant's amendment filed on **8/3/2010**. In particular, **Claims 8 and 14** have been amended to recite the water insoluble polymer as a phase separation structure formed within the hydrogel, **Claims 19-20 and 23-24** have been amended to recite the ratio of the monomer having a stimuli-responsive functional group to the water-insoluble polymer, rather than the inverse, and ***new* Claims 25 and 26** have been added specifying the members of the group from which the water-insoluble polymer is selected. New Claims 25 and 26 are supported at page 9, paragraph 3, respectively. These limitations were not present in the claims at the time of the preceding Office Action. Thus, the following action is properly made **FINAL**.

Specification

2. The amendment filed **8/3/2010** is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The amendment changes paragraph 45 of the specification from reading:

the volume ratio of the water insoluble polymer (A) to the stimuli-responsive polymer or the monomer having a stimuli-responsive functional group (B) is preferably 100:5 to 100:100,…

to reading:

the stimuli-responsive polymer or the monomer having a stimuli-responsive functional group (B) to volume ratio of the water insoluble polymer (A) is preferably 100:5 to 100:100.

There is no basis to change the specification from reading that the ratio of A to B is a given value to reading that the ratio of B to A is that same given value. This fundamentally changes the originally filed subject matter. Applicant has cited at page 4, paragraph 59-60, 66-67, and page 5 paragraphs 73-74 (this is in the PG publication, the specification as filed has these examples on page 12, paragraph 5-6, page 13, paragraph 5-6, and page 14, paragraph 5-6), examples having a ratio of B:A of 100:40. Although this specific value falls within the amended range in the case of acrylic acid as the stimuli-responsive monomer, and several polymers as the water-insoluble polymer, this is by no means adequate support to invert the entire fundamental recitation as originally filed, for all stimuli-responsive polymer or monomer, and all water insoluble polymers.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. **Claims 8, 14, 19-20 and 23-24** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With respect to Claims 8 and 14, the specification supports incorporating a water-insoluble polymer into the stimuli-responsive polymer gel, (see p. 7 par 1, p. 9 par 2) and the stimuli-responsive polymer containing water-insoluble polymer, either as an island-sea morphology or as an interpenetrating network. (See p. 10 par 3) The specification does not appear to support the action of ***forming*** a phase separation structure within the hydrogel. This language is indicative of taking action to form the polymer within the hydrogel, and the specification describes incorporation of the water-insoluble polymer. The language "wherein the water insoluble polymer is contained within the hydrogel," or describing either of the recited morphologies, or the language "wherein the water insoluble polymer is incorporated within the hydrogel" would be supported by the specification as filed.

With respect to Claims 19-20 and 23-24, the original specification as filed does not support the change to the dry volume ratio of the stimuli responsive monomer to the water insoluble polymer. (See the discussion of the same change in language, above, in paragraph 2.) Furthermore, the amendment has not remedied the previous new matter issue. Specifically the claims were amended to recite the ***dry*** volume ratio. The

specification as originally filed does not support the newly amended term of a dry ratio, and there is no mention of the use of dry ratio on page 12, par 3, where the volume ratio of these two components is discussed. The examples give a dry volume for the polymethyl methacrylate polymer, polystyrene polymer, or poly(vinylidene fluoride) polymer, corresponding to 40% of a volume of acrylic acid. This is not commensurate in scope with the claims for several reasons. First, the only dry volume ratio given in the examples is 40:100, which does not span the broad range given in claims 19 and 23, as it provides a ratio at only a single point. Furthermore, in the entirety of the current claims, nowhere are recited specific polymer species. The only polymer recited as the stimuli-responsive polymer appears to be acrylic acid. Furthermore, in the specification, the water-insoluble polymer is recited as poly(methyl methacrylate), polystyrene, and poly(vinylidene fluoride) (see p. 11, par 2) The stimuli-responsive polymer added as a monomer is acrylic acid, *inter alia*. (See p. 10) Claims 20 and 24 recite the water-insoluble polymer is 100 and the stimuli responsive monomer is 10 to 60. In the examples, the ratio is 0.4 mL of water-insoluble polymer, and 1 mL of stimuli responsive polymer (or 40:100). This does not fall within the instantly claimed range given in Claims 20 or 24, and therefore it does not appear to constitute an example of the instant claims. Should applicant wish to recite "the dry volume ratio of acrylic acid monomer to the water insoluble polymer is 100:40," this would be supported by the examples and specification as originally filed.

Claim Rejections - 35 USC § 102

4. **Claims 8, 11, 14, 18 and 25-26** are rejected under 35 U.S.C. 102(b) as being anticipated by **Wu et al**. (**US 2002/0001571**).

The rejection of **Claims 8, 11 and 14** is adequately set forth in **paragraph 2** of the office action mailed **3/20/2009**, **paragraph 3** of the office action mailed **10/29/2009**, and **paragraph 3** of the office action mailed **5/3/2010**, and is incorporated here by reference.

With respect to *amended* Claims 8 and 14, Wu teaches that the insensitive polymer is incorporated within the stimuli-responsive polymer particle. (See abstract) Based on applicant's specification, at page 7, paragraph 1, it appears that incorporation of the water-insoluble polymer into the stimuli responsive polymer hydrogel is consistent with applicant's invention and the forming of the separation structure within the hydrogel. The second polymers of Wu include polysaccharides and its derivatives, cellulose and its derivatives, polyesters, anhydrides, polyurethane, poly(lactic acid) and the like. (See par [0015], par [0041]) Cellulose is a long polymeric chain which has pendant -OH groups. While these can participate in hydrogen bonding with other cellulose chains, this does not constitute a cross-linking point as it is typically recognized by one of skill in the art, where a covalent chemical bond is formed. Thus cellulose, at least, constitutes a polymer having no cross-linking point.

Claim Rejections - 35 USC § 103

5. **Claims 8 and 10-26** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Turner et al**. (**US 6,331,578**).

The rejection is adequately set forth in **paragraph 5** and **paragraph 6** of the office action mailed **3/20/3009**, and **paragraph 6** of the office action mailed **10/29/2009**, and **paragraph 4** of the office action mailed **5/3/2010,** and is incorporated here by reference.

With regard to *amended* to Claims 1 and 14, applicant describes the phase separation structure within the polymer hydrogel, specifically that it may be an island-sea structure, or an interpenetrating network structure. (See specification, p. 10, par 3) Turner describes an interpenetrating network of a hydrophobic polymer and a hydrophilic polymer (see col 6 line 25-27) and semi-IPN networks. (See col 9 line 11-37)

With regard to *amended* Claims 19-20 and 23-24, Turner teaches that the hydrophilic to hydrophobic ratio in the dry material (or in the non-swelled state), in a preferred embodiment, varies from 1:9 to 9:1. (See col 12 line 41-52) This is consistent with a ratio of stimuli-responsive component (hydrophilic) to water-insoluble polymer (hydrophobic) of 100:90 to 100:1.11. This encompasses applicant's instantly claimed ranges. It is well settled that where the prior art describes the components of a claimed compound or compositions in concentrations within or overlapping the claimed concentrations a prima facie case of obviousness is established. See *In re Harris*, 409 F.3d 1339, 1343, 74 USPQ2d 1951, 1953 (Fed. Cir 2005); *In re Peterson*, 315 F.3d

1325, 1329, 65 USPQ 2d 1379, 1382 (Fed. Cir. 1997); *In re Woodruff*, 919 F.2d 1575, 1578 16 USPQ2d 1934, 1936-37 (CCPA 1990); *In re Malagari*, 499 F.2d 1297, 1303, 182 USPQ 549, 553 (CCPA 1974)

With regard to *new* Claims 25 and 26, Turner's hydrophobic polymers include polystyrene, *inter alia*. (See col 9 line 48)

Response to Arguments

6. Applicant's arguments filed **8/3/2010** have been fully considered. Specifically, applicant argues

(A) The specification has been amended to clarify that "the dry volume ratio of the monomer having a stimuli-responsive functional group to the water insoluble polymer" is within the claimed ranges. Accordingly the rejection under 112, first paragraph should be withdrawn.

(B) Applicants have amended Claims 8 and 14 to recite that the phase separation structure is formed within the hydrogel. Wu does not disclose or suggest a water insoluble polymer formed within the hydrogel. The Office asserts that Wu teaches a second hydrophobic polymer incorporated into a stimuli-responsive polymer and acting as a matrix for the stimuli-responsive polymer. Contrary to this assertion, Wu discloses a composite polymer system in which already polymerized stimuli-responsive particles are mixed with a second, hydrophobic polymer to form a composite membrane. Wu nowhere discloses or suggests that the second polymer is incorporated

into or formed within the stimuli responsive polymer. Furthermore, Wu does not disclose or suggest a water insoluble polymer without a cross-linking point.

(C) Applicant's traverse the rejection set forth over Turner because Turner does not disclose a water-insoluble polymer having no cross-linking point. The office asserts that because Turner teaches polystyrene as the hydrophobic host network, which is one of the water insoluble polymers disclosed in the present specification, polystyrene can not have a crosslinking point. On the contrary, Turner teaches that the hydrophobic polymer may be cross-linked (Col 9, lines 27-29 and 39-67, col 10, lines 1-10) In fact, Turner teaches a preferred embodiment where all polymeric components are crosslinked, and the host polymer network is chosen from a group including polystyrene. Thus polystyrene can be cross-linked depending on its physical properties. Furthermore, the office asserts that Turner teaches semi-IPNs in which one or more components remains linear, and it would be obvious to employ the hydrophobic component as the linear component. The office pieces together portions of Turner teaching bicontinuous, hydrophilic-hydrophobic IPN membranes, and teaching semi-IPNs. Thus one of ordinary skill in the art would have no reason to combine Turner's teachings.

7. **With respect to argument (A),** applicant's arguments have been considered but are ***not*** **persuasive**. First, the rejection was over the ratio being calculated on a dry basis. Applicant's amendment to the specification changes the ratio from A/B to B/A, but does not add the term "***dry*** volume ratio" and therefore it is not clear how applicant

intends this amendment to overcome the rejection for failure to comply with the written description requirement. Additionally, the amendment to the specification and the analogous amendment to the specification is not supported by the original specification as filed. Thus even were the specification and claims to match at the current time, neither are supported by the specification and claims as originally filed. (See the discussion in paragraphs 2 and 3, above)

With respect to argument (B), applicant's arguments have been considered but are ***not*** **persuasive**. Contrary to applicant's assertion that Wu nowhere discloses or suggests that the second polymer is incorporated into the stimuli responsive polymer, in the abstract, Wu teaches that the insensitive polymer is ***incorporated within*** the stimuli-responsive polymer particle. The claim language and support in the specification, from which the meaning is inferred, of amended Claims 8 and 14, as it currently stands, do not specify the polymerization status (already polymerized or not polymerized) of the water insoluble polymer. Furthermore, in the examples, the water-insoluble polymer appears to be added as an already polymerized structure as well. For example, on page 12, paragraph 5-6, the water-insoluble polymer is added as poly(methyl methacrylate) which is a polymer, or already polymerized methyl methacrylate monomers. This is also true for Example 2 and 3, on the following pages. Therefore it does not appear that the teachings of Wu to add an already polymerized water-insoluble polymer are contrary to the instant Claims. Wu teaches a variety of polymers as the second, water-insoluble polymer, and these include those having no crosslinking point. (See the discussion of Wu, above in par 4) In the interest of

compact prosecution, it is noted that Wu does not teach any of poly(methyl methacrylate), polystyrene, or poly(vinylidene fluoride) as the water insoluble polymers (see Wu, par [0015]), those polymers which are the subject of applicant's Examples, and new Claims 25-26. Therefore incorporating the subject matter of Claims 25 and 26 into Claims 8 and 14, respectively, would overcome the rejection over Wu.

With respect to argument (C), applicant's arguments have been considered but are ***not*** **persuasive**. With respect to Turner's polystyrene, first if there is a polystyrene which has no crosslinking point available, and used by applicant, then Turner's polystyrene reads on polysturene including this particular embodiment. Furthermore, Turner teaches preferred hydrophobic components (col 9 line 39-47) and then goes on to discuss suitable crosslinking agents for the hydrophobic material (see col 9 line 49 – col 10 line 10) which includes crosslinking agents for for vinyl containing siloxanes (col 9 line 52), other siloxanes (col 9 line 54), PTMO, and other siloxanes, (col 9 line 55). Crosslinkers enumerated for polystyrene are conspicuously absent. Thus it would not be immediately evident to one of ordinary skill in the art to use a crosslinkable polystyrene, were one to be chemically feasible. With regard to the chemical feasibility of a crosslinkable polystyrene, polystyrene is composed of phenyl groups and a backbone of -C-C- bonds, and for that reason it is fairly chemically inert. This is because the benzene rings are stable due to resonance structure, and the backbone has no available double bonds or readily reactive groups with which to interact with most chemistry. Typically, in order to produce a crosslinkable polystyrene, some other

more reactive monomer such as divinylbenzene must be included. Therefore a polystyrene homopolymer would not be crosslinkable.

With respect to applicant's assertion that Turner's teaching of bicontinuous, hydrophilic-hydrophobic IPN membranes and semi-IPNs are pieced together from disparate parts of the disclosure, it is noted that Turner discloses a bicontinuous hydrophilic-hydrophobic IPN membrane in the same paragraph as semi-IPNs. Specifically, in this paragraph, Turner discusses the bicontinuous IPM membranes, and then goes on to teach that semi-IPNs may also be prepared. That these appear in the same paragraph, and that the semi-IPN discussion is presented as an alternative to the embodiment in which Turner teaches bicontinuous IPN membranes where both are crosslinked. Specifically, Turner indicates that semi-IPNs are suitable where drug delivery or matrix applications involving the use of stimuli, in order to tailor the response profile. (See col 9 line 32-35) Based on both the close proximity of these teachings (in the same paragraph) and Turner's teachings that they are explicit alternatives, it would be obvious to one of ordinary skill in the art to take note of Turner's teaching of a semi-IPN as an alternative embodiment of the invention using the remainder of Turner's teachings.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darcy D. LaClair whose telephone number is (571)270-5462. The examiner can normally be reached on Monday-Friday 8:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Milton I. Cano/
Supervisory Patent Examiner, Art Unit 1763

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/DDL/